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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/839,638	04/20/2001	Michael DiCuccio	P-11549.00	2152

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EXAMINER

SAADAT, CAMERON

ART UNIT PAPER NUMBER

3713

DATE MAILED: 04/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/839,638

Applicant(s)

DICUCCIO ET AL.

Examiner

Cameron Saadat

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 1-9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

In response to the declaration filed 2/10/2004, claims 1-15 are pending in this application. Non-elected claims 1-9 are withdrawn from consideration.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10-13 are rejected under 35 U.S.C. 102(e) as being anticipated by Arai (Intelligent Assistance for Intravascular Tele-surgery and Experiments on Virtual Simulator).

Regarding claim 10, Arai discloses a method of designing a surgical instrument, the method comprising: creating a computer model of the surgical instrument; using the model of the surgical instrument in a surgical simulation; changing the computer model of the surgical instrument; and using the changed model in a surgical simulation (P. 103 ¶4 – P 104, ¶5)

Regarding claim 11, Arai discloses a method and process wherein the surgical simulation comprises haptic feedback (P. 103 ¶4).

Regarding claim 12, Arai discloses a method further comprising defining a goal for the surgical instrument and assessing the performance of the model of the surgical instrument in achieving the goal and the performance of the changed model of the surgical instrument in achieving the goal (P. 103 ¶4 – P 104, ¶5; Table 1; Fig. 12-13).

Regarding claim 13, Arai discloses a method further comprising comparing the assessments (See Table 1; Fig. 12-13).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arai (Intelligent Assistance for Intravascular Tele-surgery and Experiments on Virtual Simulator) in view of Jang et al. (USPN 6,165,406; hereinafter Jang)

Regarding claim 14, Arai discloses a surgical instrument made by a process comprising: creating a computer model of a first version of the surgical instrument; using the computer model in a surgical simulation; changing the computer model to create a second version of the surgical instrument; using the change computer model in a surgical simulation (P. 103 ¶4 – P 104, ¶5). Arai discloses a method of modeling and conducting experiments on a prototype of a surgical instrument under various conditions, but does not explicitly disclose that the prototype is *manufactured*. However, it is an obvious and well known step to manufacture a specific version of a prototype. Furthermore, Jang discloses a method of computer-aided design for prototyping and manufacturing medical diagnostic instruments (Col 1, lines

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11, 41-51). In view of Jang it would have been obvious to an artisan to modify the prototype described in Arai, by advancing to the next step to manufacture a simulated prototype, wherein the experiments conducted on the prototype allow identification of the most effective parameters through simulation, and thereby reduces manufacturing time and cost.

Regarding claim 15, Arai discloses a process wherein the surgical simulation comprises haptic feedback (P. 103 ¶4).

Response to Arguments

The Declaration filed on 2/10/2004 under 37 CFR 1.131 is sufficient to overcome the Anderson reference. Therefore, the rejection in view of Anderson has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- Murray et al. (USPN 6,675,135) – disclose a design method.
- Nagle et al. (Case Studies in Medical Instrument Design) – disclose methods of medical product development.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cameron Saadat whose telephone number is 703-305-5490. The examiner can normally be reached on M-F 8:00 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Teresa J Walberg can be reached on 703-308-1327. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CS


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